The Cost of Prescription Drugs in Context

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Since 2000, biopharmaceutical companies have brought

MORE THAN 500 NEW TREATMENTS AND CURES

to U.S. patients

In the last 100 years, medicines have helped raise average U.S. life expectancy ***from 47 years to 78 years****

5 year cancer survival rates are ***up 39 percent across all cancers*****

Death rates for HIV/AIDS and cancer have fallen ***85 percent and nearly 22 percent since their peaks in 1995 and 1991******

New hepatitis C therapies have cure rates of ***more than 90 percent*******

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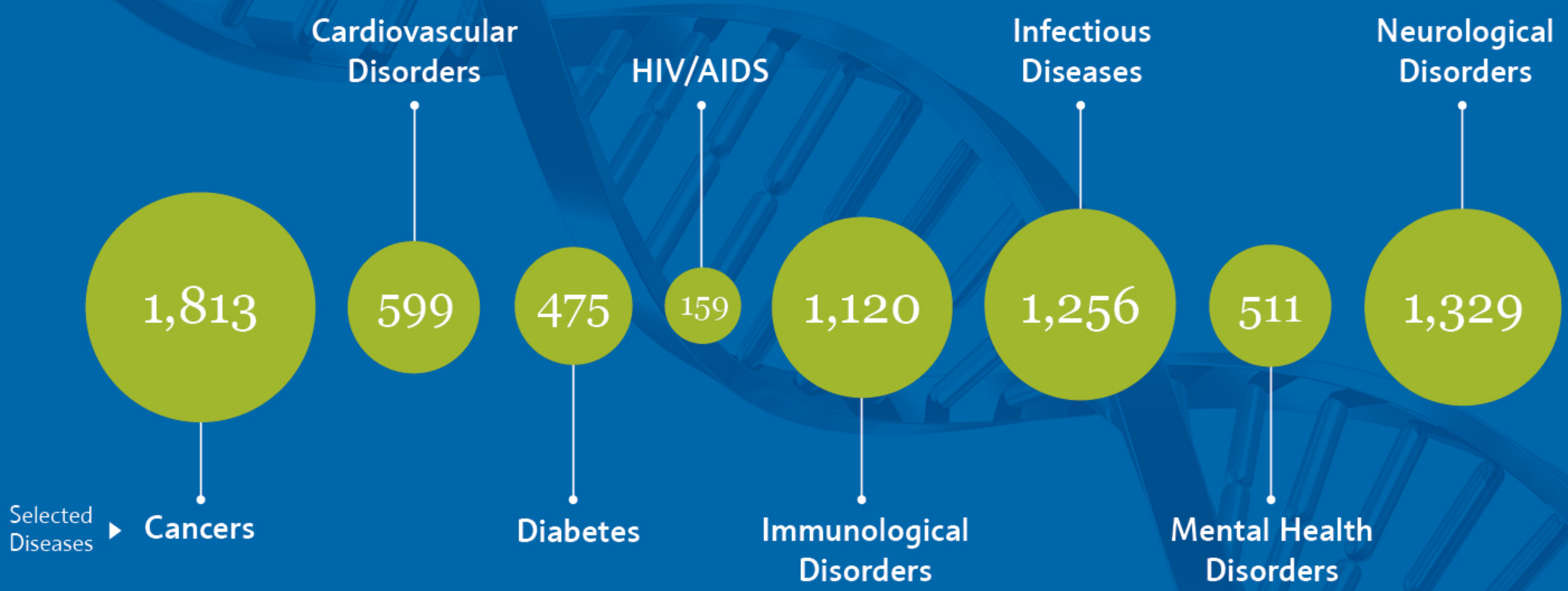
*Source: CDC
**Source: American Cancer Society
***Sources: CDC; NCI
****Source: FDA

TODAY MORE THAN 7,000 MEDICINES

are in development around the world

Medicines in Development*



*Defined as single products which are counted exactly once regardless of the number of indications pursued

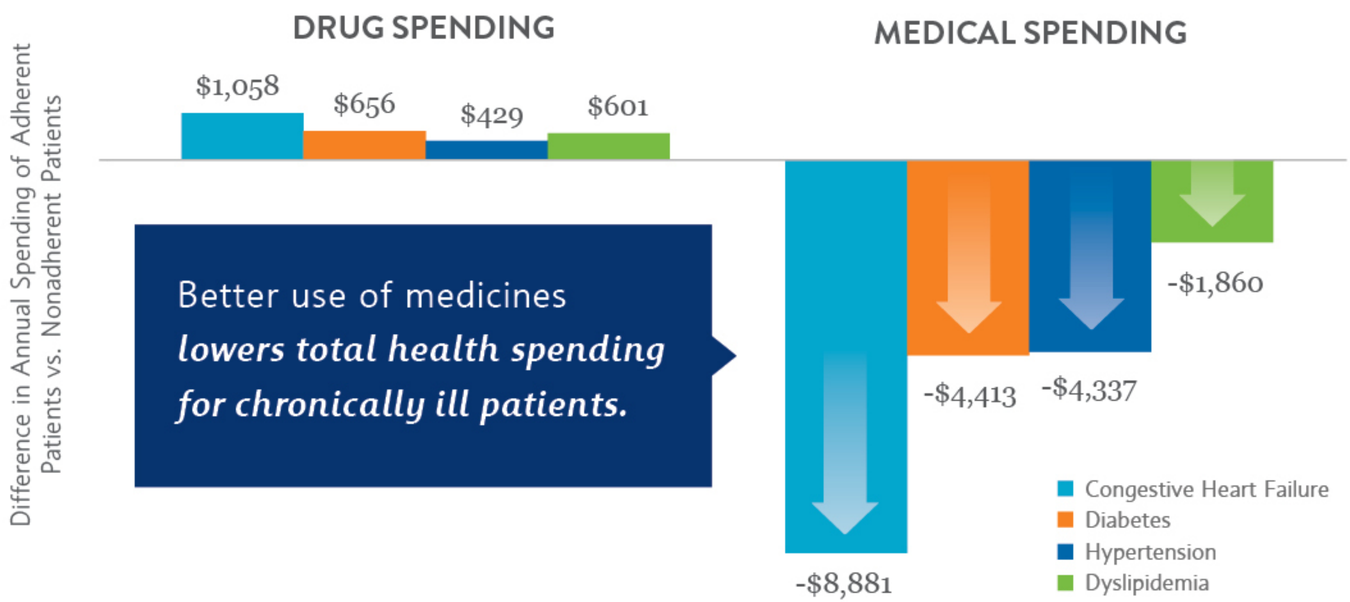
Source: Adis R&D Insight Database

Medicines save lives and help patients

AVOID EXPENSIVE HOSPITALIZATIONS AND EMERGENCY ROOM VISITS

THE U.S. HEALTH CARE SYSTEM COULD SAVE $213 BILLION ANNUALLY IF MEDICINES WERE USED PROPERLY*

Adherence to Medicines Lowers Total Health Spending for Chronically Ill Patients**



*Source: IMS Institute for Healthcare Informatics. Avoidable costs in US healthcare: the $200 billion opportunity from using medicines more responsibly.;

**Source: Roebuck MC, et al. Medication adherence leads to lower drug spending. *Health Affairs*. 2011;30(1):-99.

HIV/AIDS:

As Treatment Improved Spending Became Sustainable

1989

The New York Times

September 15, 1989

AIDS Treatment Costs Put at $5 Billion a Year

"We have got to get our act together now because the medical system is going to be crushed in two years."

–Daniel Hoth, director of the division of AIDS at the National Institute for Allergy and Infectious Diseases

‘"If we don't act now, we will be soon rationing health by queuing," ...

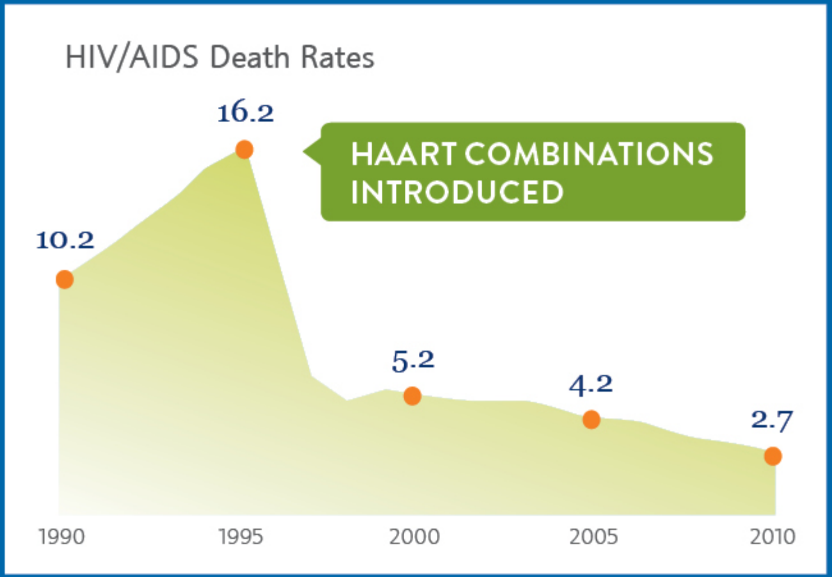
‘'People will wait longer and longer in the emergency rooms, more people will die, the whole level of care will decrease significantly." He called it ''a downward spiral of effects which we cannot afford."

–Dr. Douglas Shenson, Montefiore Medical Center

Today

"WE USED TO THINK HIV COSTS WOULD OVERWHELM US....BUT WE FIGURED IT OUT AND LET DRUG DEVELOPMENT PROGRESS."

– Ira Klein, M.D., M.B.A., FACP, Aetna

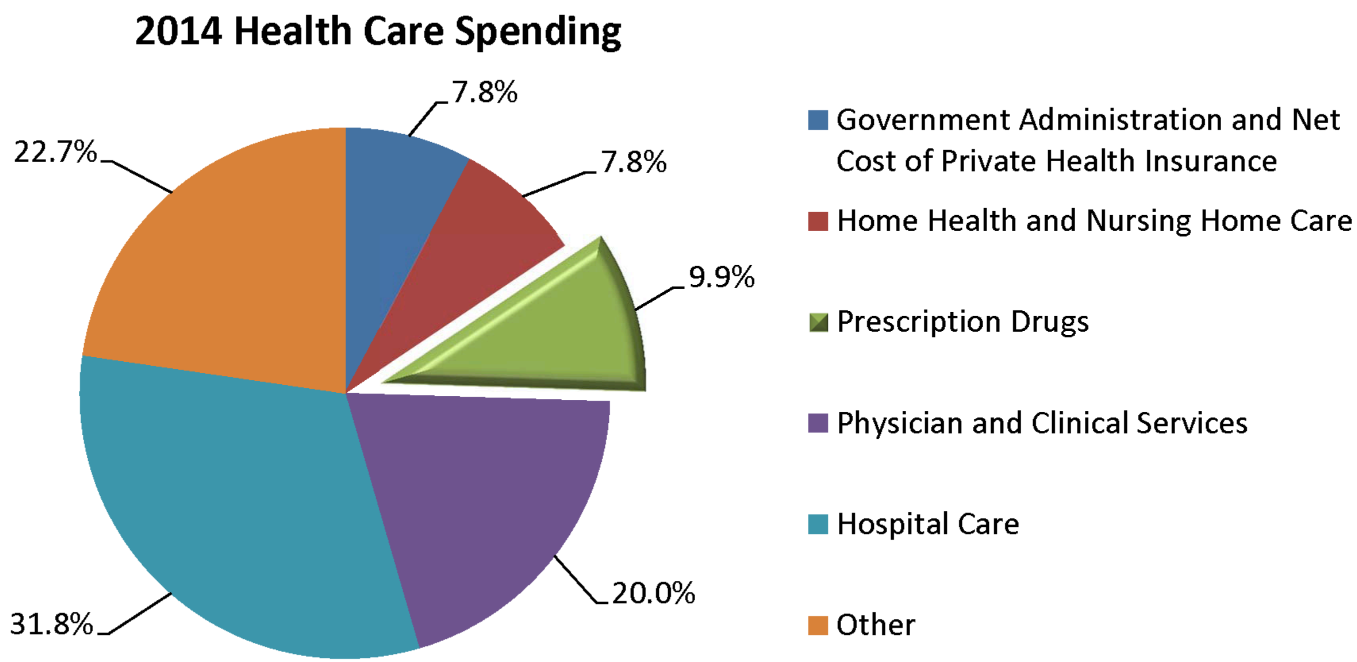


Putting Prescription Drug Spending in Context

RX COSTS HISTORICALLY AND GOING FORWARD

Retail Spending on Prescription Medicines Is a Small Share of Total US Health Care Spending

Retail brand & generic prescription medicines along with pharmacy costs account for about 10% of health care spending in America today, the same percentage as in 1960.



*Other includes dental, other professional services, other health, residential, and personal care, durable medical equipment, other non-DME products, government public health activities, and investment expenses.

PhRMA analysis of CMS data. National health expenditures by type of service and source of funds, CY 1960-2014 Baltimore, Md.: CMS; 2015. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2014.pdf

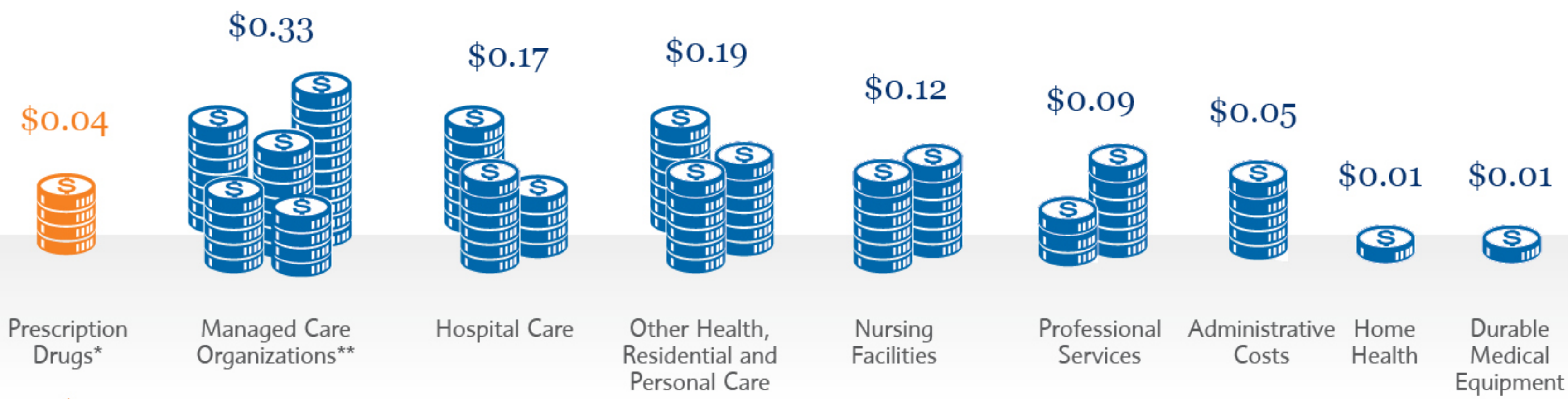
Spending on prescription medicines in Medicaid accounts for

ONLY ABOUT 4% OF ALL MEDICAID SPENDING

Spending on prescription medicines is

A SMALL SHARE OF TOTAL MEDICAID SPENDING

Health Care Dollar, 2014



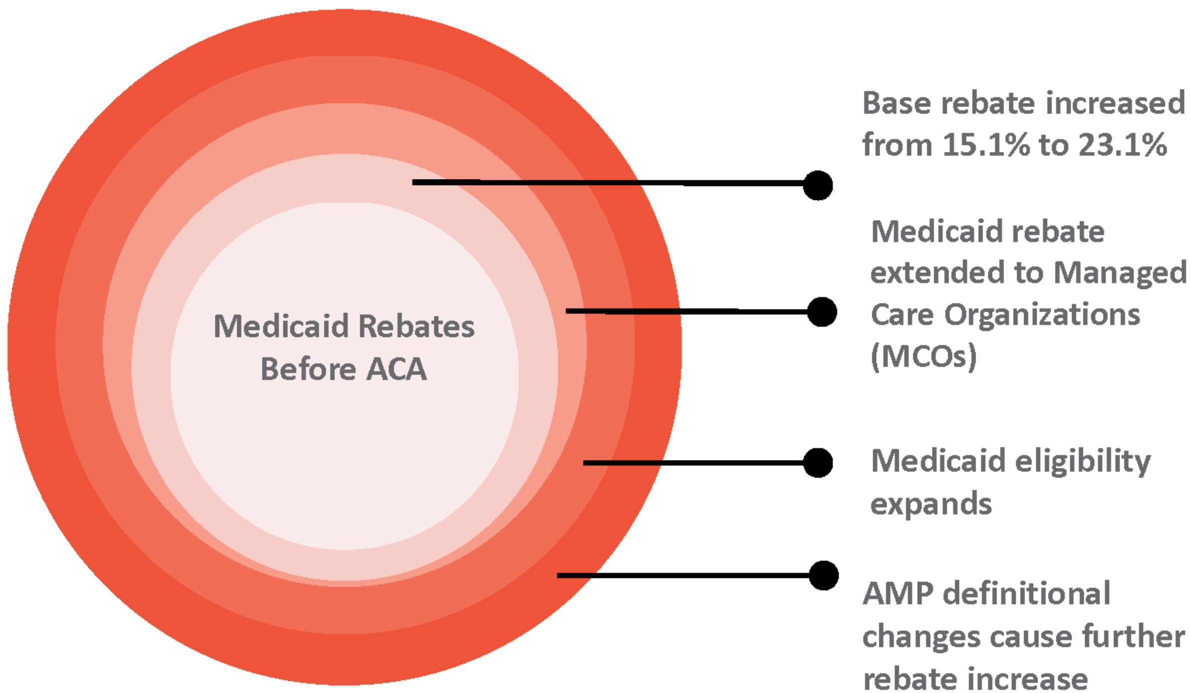
Prescription medicines account for just over 4 percent of total Medicaid spending and this share is projected to remain stable through the next decade

*Prescription medicine figures represent post-rebate totals
**Excluding pharmacy component

Source: Prepared by The Menges Group and pulled from data included in the Medicaid Financial Management Report (FMR) compiled by CMS. The FMR is broken down into several dozen service categories, which were grouped into broader categories for inclusion in the chart. The state summary data sheet figures were largely derived from the State Drug Utilization Data CMS posts quarterly.

Medicaid Rebates on Prescription Medicines Increase Substantially Under ACA

Independent analysts estimate the expansion of Medicaid prescription drug rebates in the Affordable Care Act could increase brand manufacturers' costs by more than $40 billion over 10 years (2012-2021).[10]



Note: Graphic is Illustrative only.
Sources: PwC Health Research Institute[10]; Medicaid.gov[11]

How the Medicaid Drug Rebate Works

FOR BRAND DRUGS

To ensure coverage of prescription medicines for Medicaid enrollees, under Federal law the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to provide rebates in exchange for Medicaid coverage of their drugs.

Basic Rebate

The Greater of:
Best Price
(Difference between AMP & Best Price)
OR
Minimum Rebate
(23.1% of AMP)

+

Consumer Price Index Rebate

Paid if the price increases by more than CPI:
Paid cumulatively to protect states from price increases higher than inflation

+

"Supplemental" Rebate

Negotiated by manufacturers for enhanced access for patients through preferred drug lists

=

2014 Rebates (Brand Only)

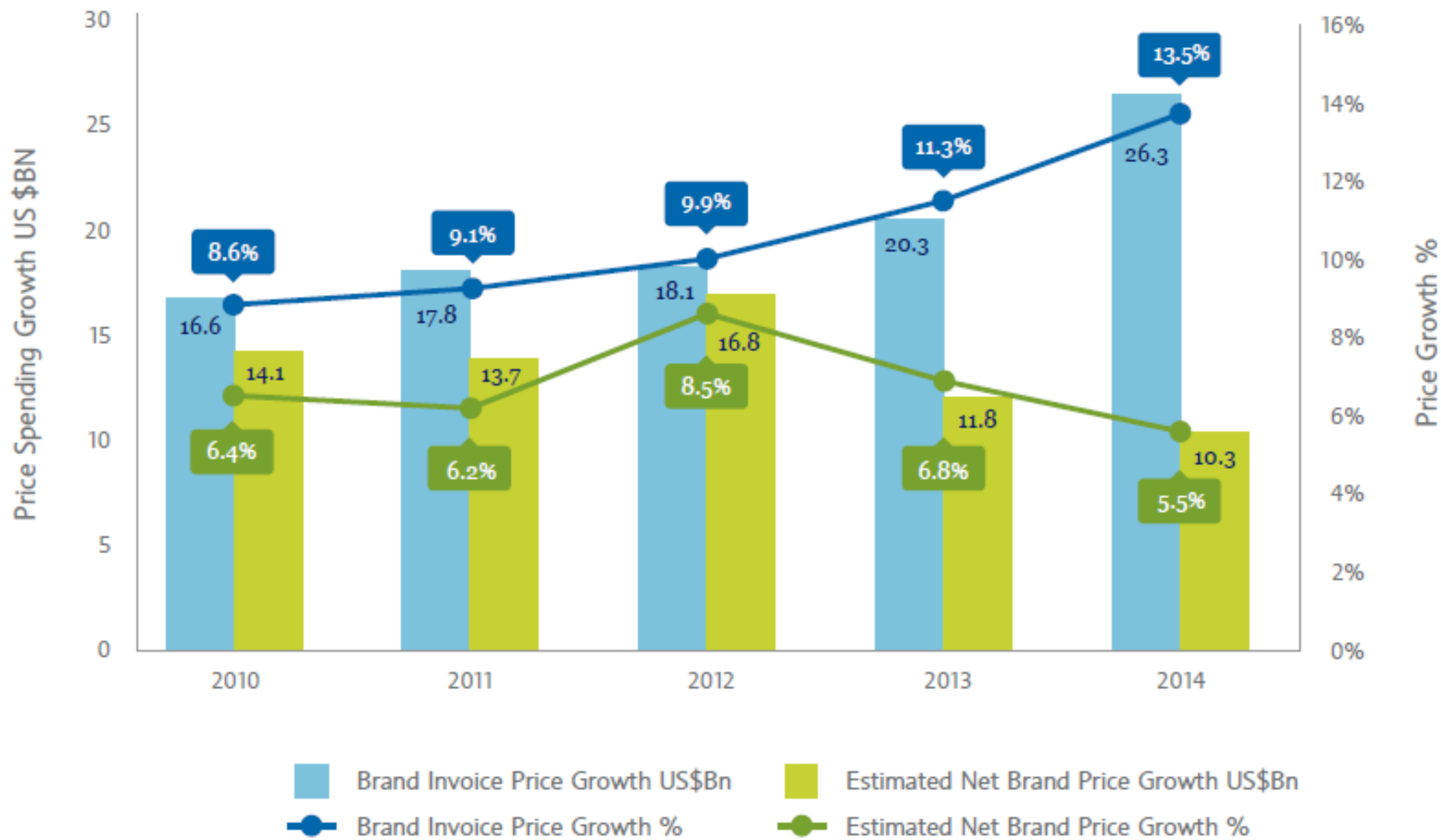
$19.4 Billion

AMP – Average Manufacturer Price
Best Price – Lowest price drug sold to any non-government purchaser excluding certain sales (VA, Part D, and 340B)

Invoiced Prices Increased in 2014,

BUT WERE OFFSET BY REBATES AND OTHER PRICE CONCESSIONS

Protected Brand Price Spending Growth



Many factors impact

THE PRICE OF MEDICINES

The calculations behind drug pricing are complex but include some of the following factors:

Prevalence of the disease and current and projected value of treatment to patients, society, and the health care system

Competitive landscape and patient benefits versus existing therapies

Severity and complexity of the disease and impact on patient quality- of-life and mortality

Degree to which drug changes medical practice, e.g., prevents other more costly medical procedures

Capital costs, e.g., specialized facilities; manufacturing, packaging, & shipping costs and infrastructure to ensure integrity of supply chain

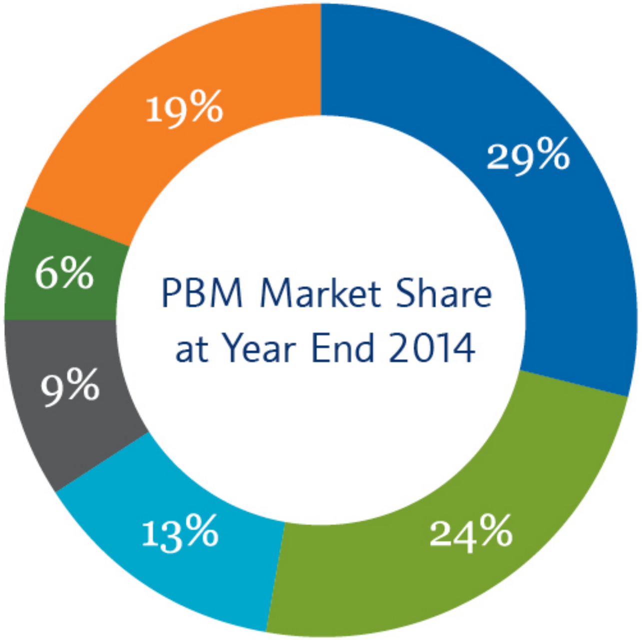
Expected Government and private discounts and rebates and utilization management procedures

R&D costs, e.g., successes and failures across therapeutic areas and over time & need to ensure sufficient returns for future R&D investment

POWERFUL PURCHASERS NEGOTIATE ON BEHALF OF PATIENTS

Negotiating power is increasingly concentrated among fewer benefit managers, with the

TOP FIVE PBMS INCREASING THEIR MARKET SHARE TO OVER 80%.



PBMs
TOP 5 MARKET SHARE 81%

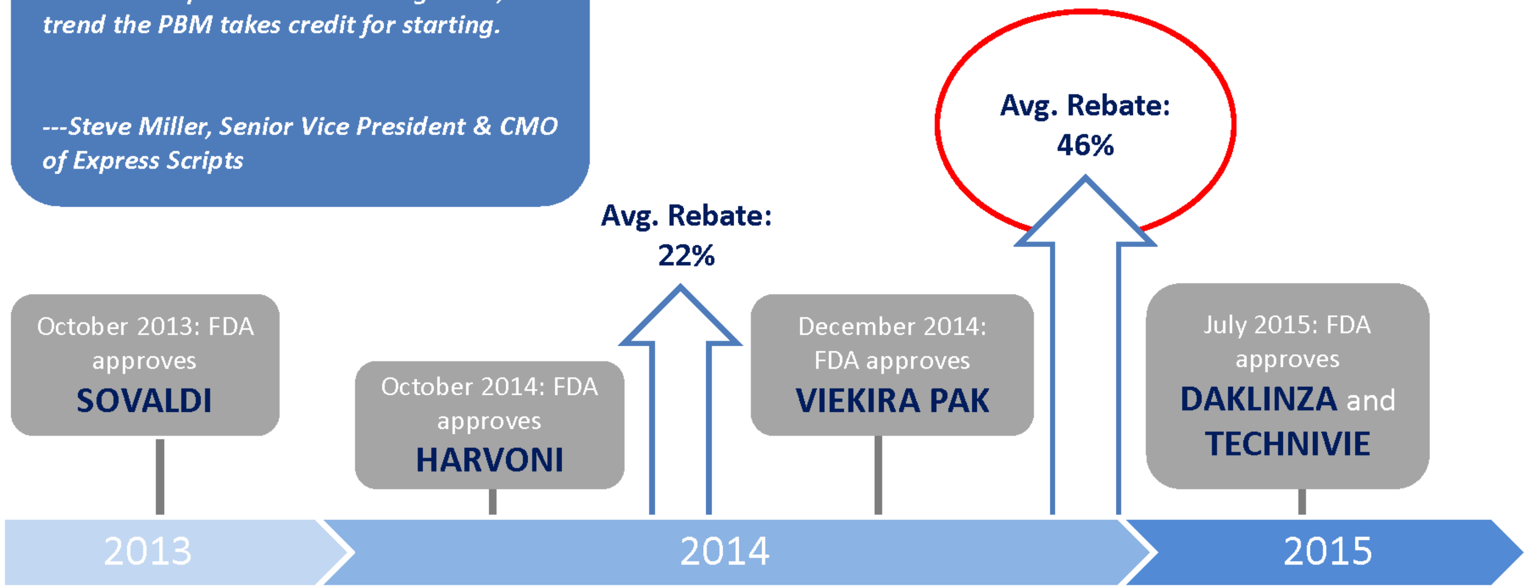
- Express Scripts, Inc.
- CVS Caremark
- OptumRx
- Catamaran Corporation
- Prime Therapeutics Inc.
- All Else

*OptumRx and Catamaran Corp. will merge to UnitedHealth Group in fall of 2015
Sources: Drug Channel Institute Study Jan. 2015
IMS Institute for Healthcare Informatics Health Study: 2014

Competition and Aggressive Payer Negotiations Reduce Net Drug Costs

Discounts and rebates significantly reduce the net prices of brand medicines. This is particularly true when new medicines enter the market. Payers and PBMs leverage competition and negotiate lower prices through the aggressive use of formulary restrictions and the threat of coverage exclusions.

> ***U.S. payers will save $4 billion this year thanks to hepatitis C cost-cutting deals, a trend the PBM takes credit for starting.***
>
> ***---Steve Miller, Senior Vice President & CMO of Express Scripts***



Sources: E. Wasserman. "Gilead Zooms Past AbbVie in Hep C Race With UnitedHealth Deal." *FiercePharma*. January 29, 2015; A. Fein. "What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing." *Drug Channels*. February 5, 2015.

CASE STUDY

Manufacturer-payer hepatitis C negotiations

What Payers Claimed Would Happen

"What they have done with this particular drug will break the country.... It will make pharmacy benefits no longer sustainable. Companies just aren't going to be able to handle paying for this drug."

–EXPRESS SCRIPTS (APRIL 2014)

"This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system."

–AMERICA'S HEALTH INSURANCE PLANS (JULY 2014)

What Actually Happened

"The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C."

–EXPRESS SCRIPTS (JANUARY 2015)

"We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary."

–PRIME THERAPEUTICS (JANUARY 2015)

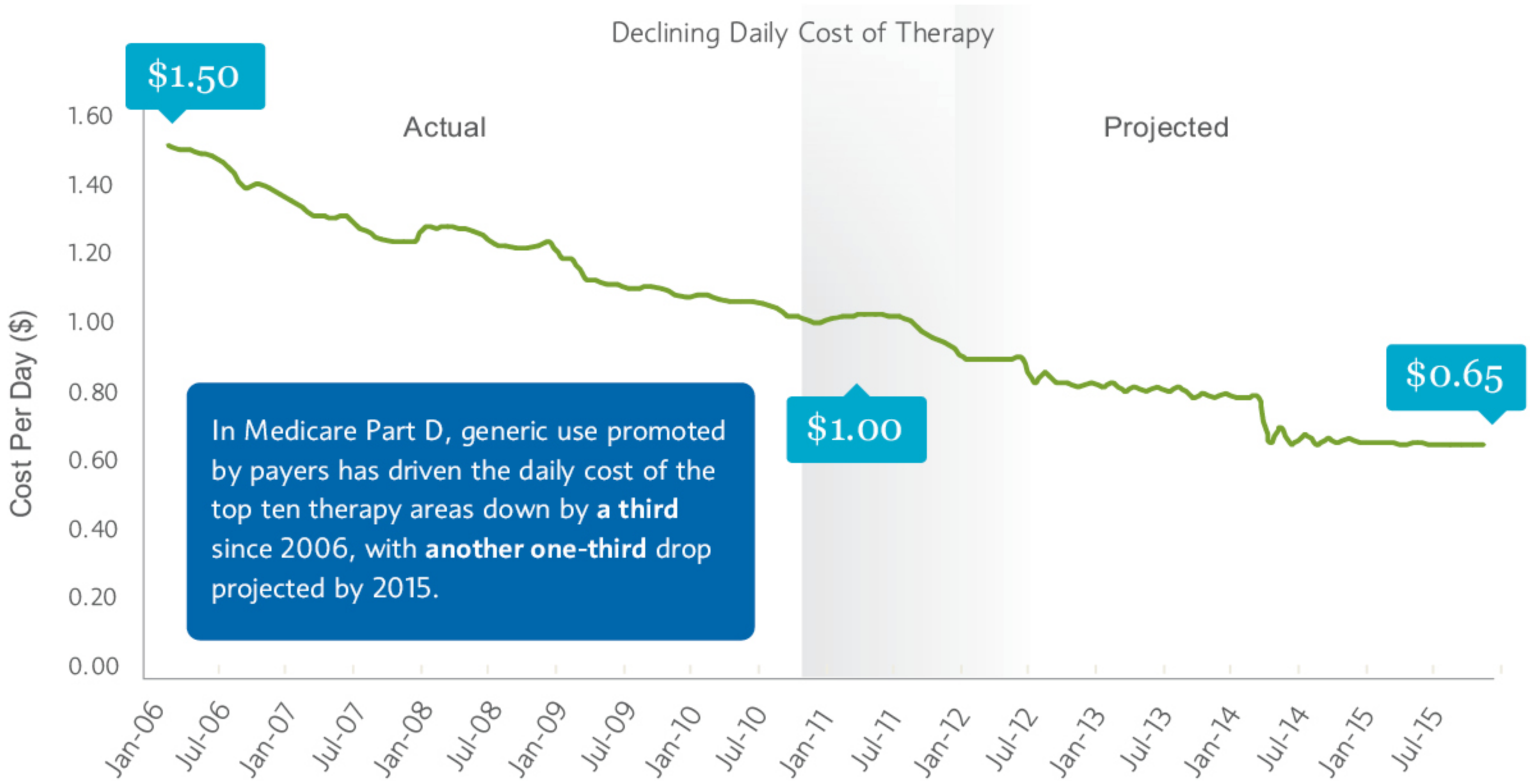
"Competitive market forces and hard-nosed bargaining" make 'tremendously effective' new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the U.S. health care system."

–THE NEW YORK TIMES EDITORIAL BOARD (SEPTEMBER 2015)

The U.S. System Promotes Innovation and Affordability through

THE PRESCRIPTION DRUG LIFE CYCLE

In the U.S. system, innovator pharmaceutical companies produce medical advances, leading to improved health for patients and, over time, generic copies that consumers use at low cost for many years.



Source: Kleinrock M. Daily cost of Medicare Part D. December 2013. IMS Institute for Healthcare Informatics.

Example

THEN & NOW

How Prescription Drug Prices Fall Significantly Over Time

Biopharmaceutical companies invest in pioneering research to bring new treatments to patients, and over time those medicines become available as lower-cost generic copies.

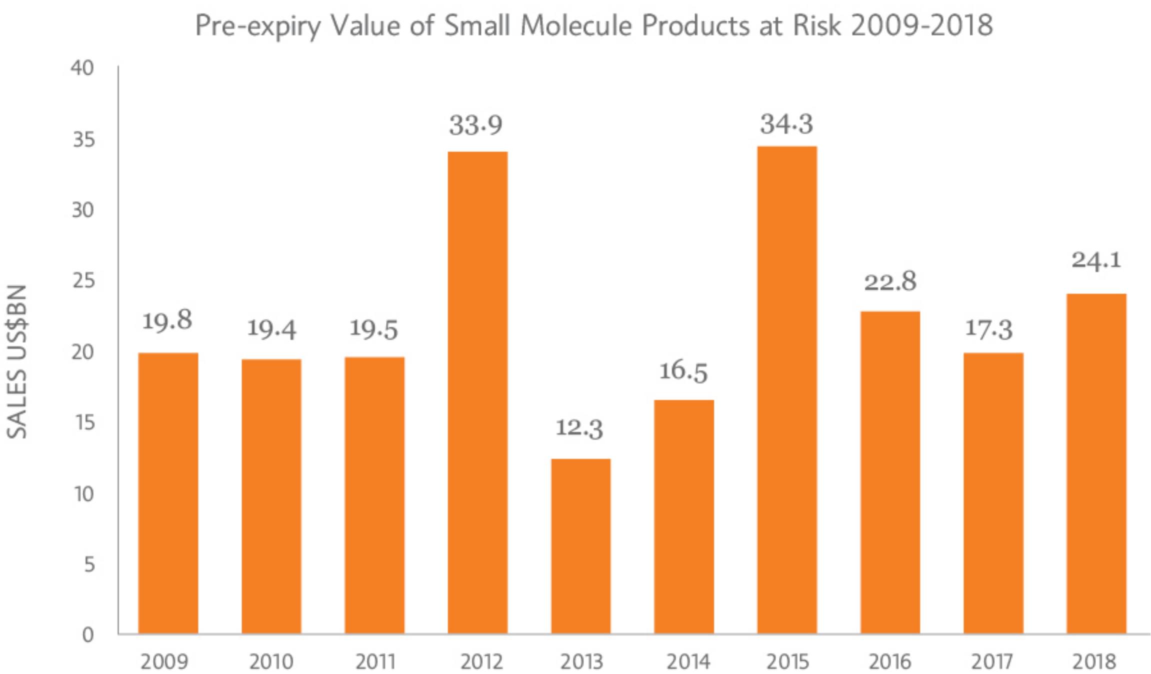
MEDICINE		BRAND NAME THEN	VS. GENERIC NOW	% CHANGE
DIOVAN HCT® *Hypertension*	2010	$87	$13	-85%
LIPITOR® *Cholesterol*	2010	$85	$4	-95%
PLAVIX® *Blood Thinner*	2011	$166	$5	-97%
SEROQUEL® *Schizophrenia*	2010	$87	$3	-97%
ZYPREXA® *Schizophrenia & Bipolar Disorder*	2010	$393	$8	-98%

Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength.
"Then" price represents the average price in the year prior to generic entry. "Now" price represents the average price in CY 2014.
Source: IMS analysis for PhRMA, May 2015

$115 Billion of U.S. Brand Sales Projected to

FACE GENERIC COMPETITION FROM 2014 TO 2018

Similar exposure in coming years to the $105Bn loss in 2009-13 (the "patent cliff") underscores continuing cost containment in the pharmaceutical sector



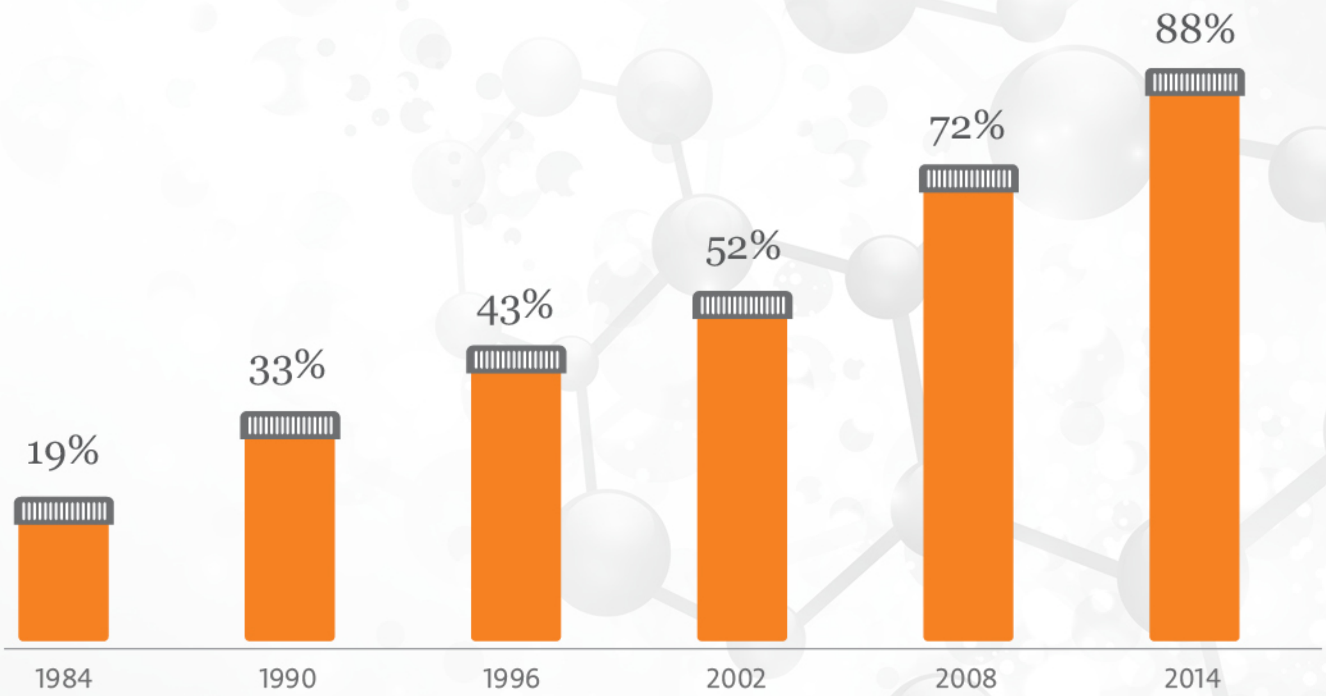
Estimates exclude additional impact of biosimilars entering the market; analysts estimate nearly 3/4 of biologic expenditures are at-risk due to loss of exclusivity before 2017

Notes: Pre-expiry sales of products are calculated for products losing exclusivity (LOE) in each year, the sales in the prior year for each product are aggregated to represent the collective industry exposure to LOE. Loss of exclusivity does not indicate generic market entry. Small molecule losses of exclusivity only.

Source: IMS MIDAS, Market Prognosis, Sep 2014

Nearly 9 Out of Every 10 US Prescriptions
ARE FILLED WITH GENERICS

Generic Share* of Prescriptions Filled 1984-2014



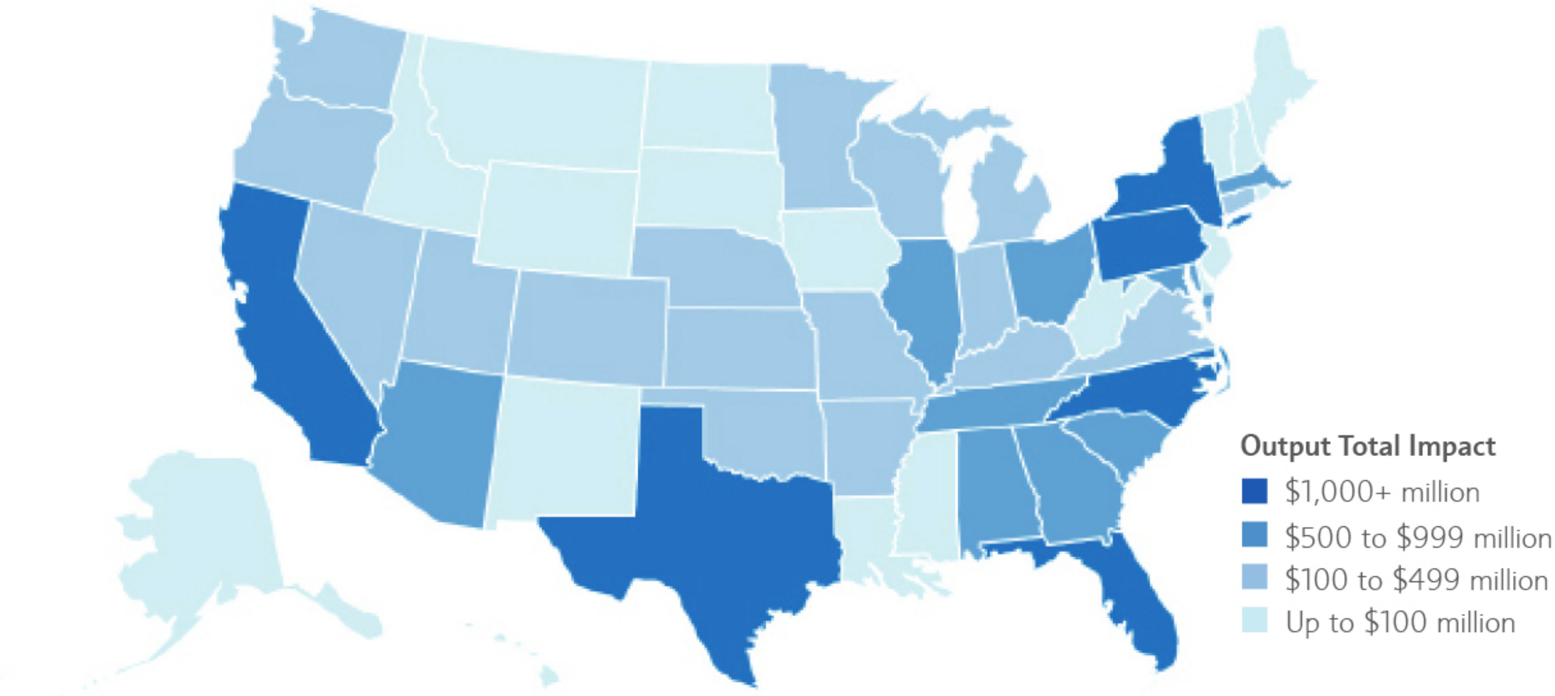
RECOGNIZING CHALLENGES & CHANGES IN THE MARKETPLACE

Industry-Sponsored Clinical Trials Contribute

SIGNIFICANT VALUE TO THE COMMUNITIES IN WHICH THEY ARE LOCATED

In 2013, the biopharmaceutical industry sponsored **6,199 clinical trials** of medicines in the United States, involving a total of **1.1 million volunteer participants** and supporting a total of **$25 billion in economic activity** spread across all 50 states and the District of Columbia.*

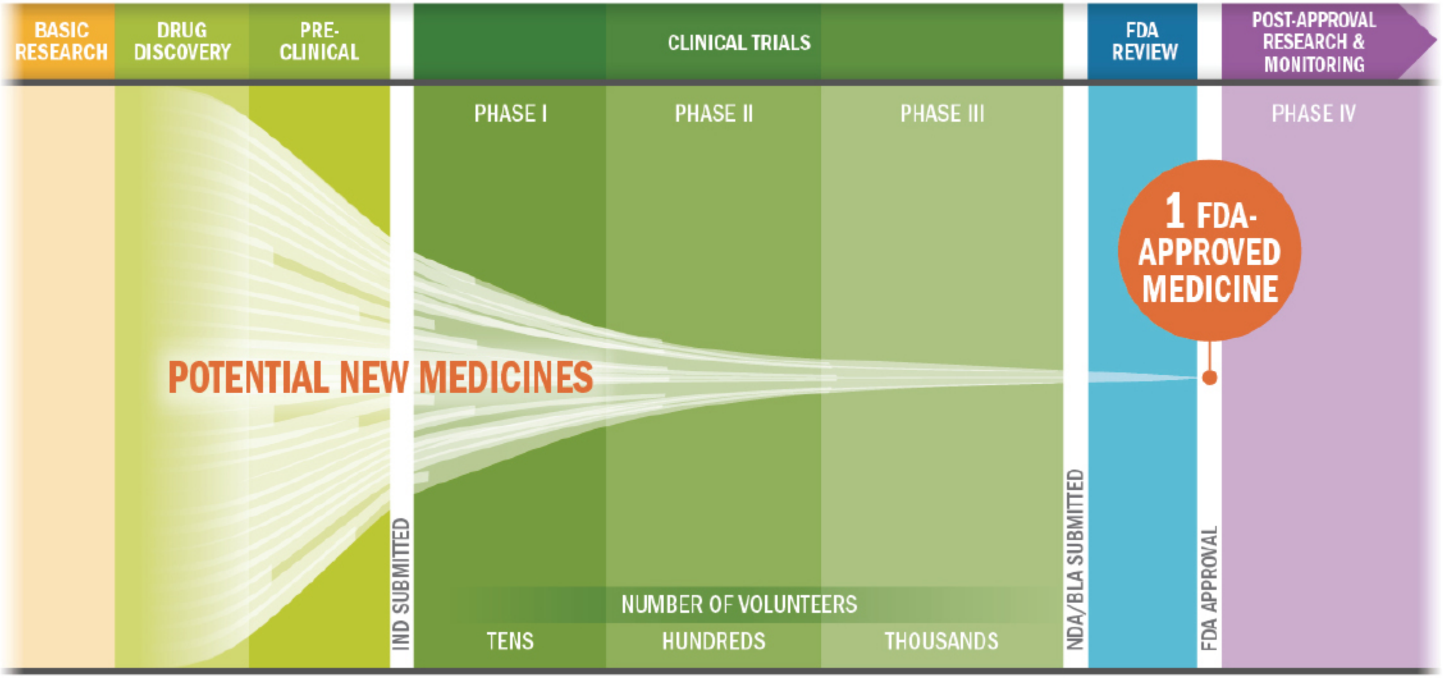
Estimated Economic Impact from Industry-Sponsored Clinical Trial Sites Across the United States, 2013



Source: Battelle Technology Partnership Practice

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine on average takes at least 10 years and costs between $2.6 billion. Less than 12% of the candidate medicines that make it into phase I clinical trials will be approved by the FDA.



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

*The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA

Medicines offer great hope, but developing

NEW TREATMENTS AND CURES IS CHALLENGING

On average, it takes more than

10 YEARS AND MORE THAN $2.6B TO RESEARCH AND DEVELOP A NEW MEDICINE*

BETWEEN 1998 AND 2014**

UNSUCCESSFUL ATTEMPTS

123
ALZHEIMER'S DISEASE

96
MELANOMA

167
LUNG CANCER

JUST 12%

of drug candidates that enter clinical testing are approved for use by patients*

SUCCESSFUL ATTEMPTS

4
ALZHEIMER'S DISEASE

7
MELANOMA

10
LUNG CANCER

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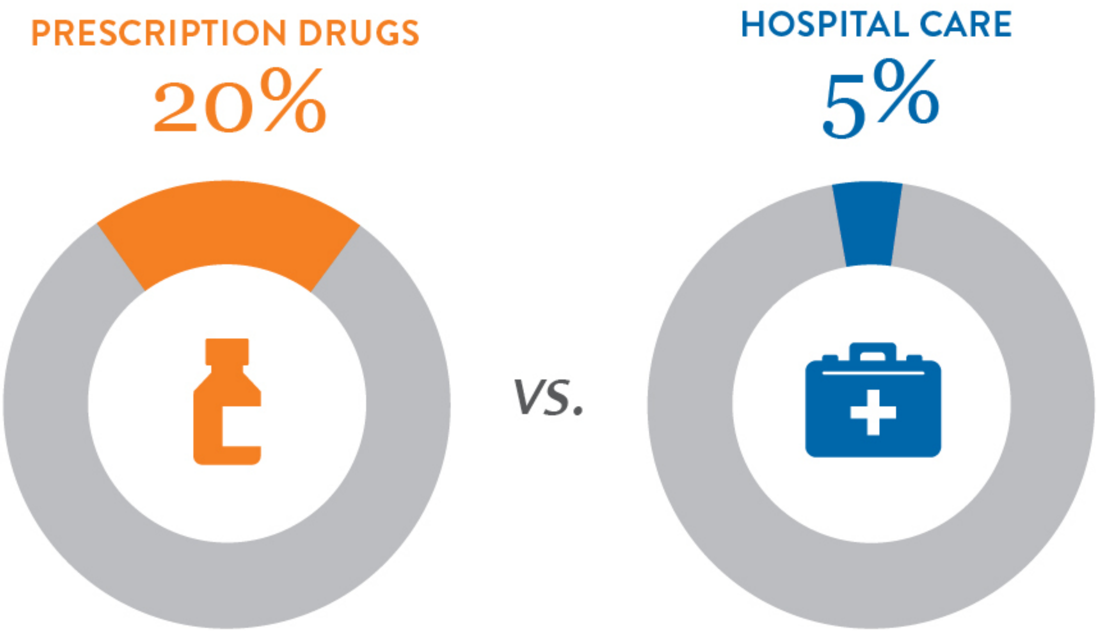
*Source: Tufts Center for the Study of Drug Development (CSDD)
**Source: PhRMA

MEDICINES ARE OFTEN SINGLED OUT BY INSURERS

for high cost sharing and restrictions on access

On average, patients pay out of pocket nearly

20 PERCENT OF THEIR TOTAL PRESCRIPTION DRUG COSTS COMPARED TO 5 PERCENT OF HOSPITAL CARE COSTS*

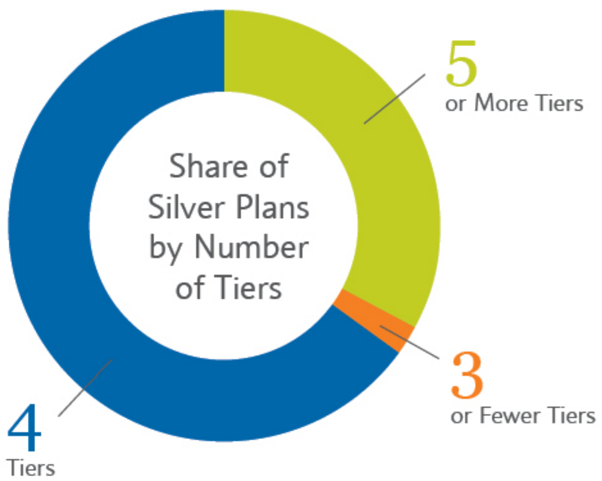


*Includes brand and generic

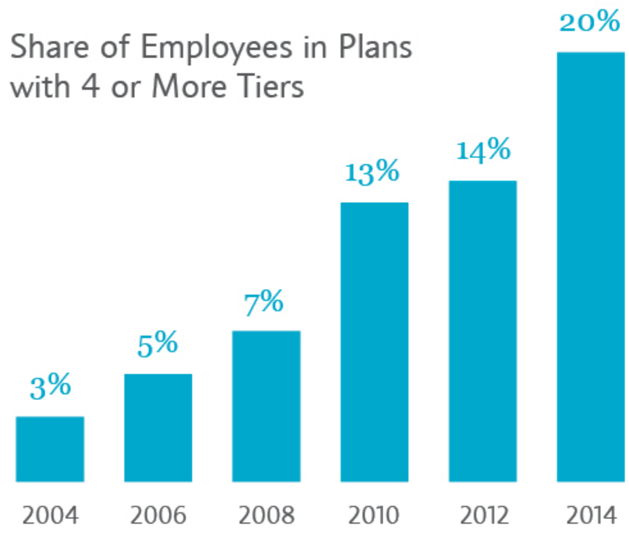
Source: PhRMA analysis based on Medical Expenditure Panel Survey (MEPS)

THE USE OF 4 OR MORE COST-SHARING TIERS*

...is the norm for plans in Health Insurance Exchanges



...and is becoming more common in employer plans



Beyond high cost sharing, barriers to access include insurer practices like prior authorization and step therapy.

*Silver Plans account for a majority of Health Insurance Exchange enrollment. "Tiers" refer to the different levels of cost sharing that plans require patients to pay for different groupings of medicines.

Sources: Avalere PlanScape® Database; Kaiser Family Foundation/Health Research & Educational Trust. Employer health benefits: 2014 annual survey. September 2014, 166.

RAPID CHANGE IN THE MARKET FOR MEDICINES

NEW TOOLS ARE BEING DEVELOPED TO CONTROL COSTS AND DRIVE VALUE

VALUE-BASED INSURANCE DESIGN	AGGRESSIVE NEGOTIATION OVER REBATES, DISCOUNTS	ACCOUNTABLE CARE ORGANIZATIONS
CLINICAL PATHWAYS	PROVIDERS AT RISK FOR RX COSTS	BUNDLED PAYMENTS

Medicines are Part of the Solution...

AND MORE CAN BE DONE TOGETHER

COST CONTAINMENT

Look at all health care costs, reduce administrative costs and waste, replicate effective cost-containment practices.

PAY FOR VALUE

Support evidence-based care and empowered patients and providers, backed by sound research and strong quality measures.

SOLUTIONS

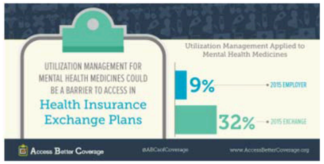
Avoid blanket policies that chill investment, and collaborate to find new approaches.

Roadmap to

PhRMA RESOURCES

Cost/Value: Resources that highlight the value medicines provide to patients, the health care system and society.

- Cost site: http://www.phrma.org/cost
- Catalyst blog: http://catalyst.phrma.org/



Access Better Coverage (ABC) Campaign: Resources and tools related to patient access in the health insurance exchanges.

- ABC site: http://accessbettercoverage.org
- Burden on Patients blog series: http://catalyst.phrma.org/burden-on-patients-access-to-medicines-in-exchange-plans
- State fact sheets: http://accessbettercoverage.org/numbers#states

From Hope to Cures: Real-life stories of patients who have overcome rare, debilitating and chronic diseases with the help of innovative medicine.

- From Hope to Cures site: http://www.fromhopetocures.org/
- I'm Not Average site: http://www.fromhopetocures.org/patients#sub-bottom
- In Your State site (state-specific content): http://www.fromhopetocures.org/in-your-state

Innovation: Resources detailing the process and importance of biopharmaceutical research and innovation.

- Innovation Hub: http://innovation.org/
- Clinical Trails: http://phrma.org/innovation/clinical-trials